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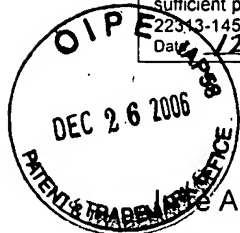
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Date: 12/21/06 Name: Jason W. Schigelone, Reg. No. 56,243 Signature: [Signature]

BRINKS
HOFER
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& LIONE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Appln. of: Thomas A. Osborne et al.

Appln. No.: 10/642,513

Filed: August 15, 2003

For: Stent and Method of Forming a Stent
with Integral Barbs

Attorney Docket No: 12730-11

Examiner: William H. Matthews

Art Unit: 3738

Mail Stop AF
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Attached is/are:

- ☒ Petition to Withdraw Finality under 37 C.F.R. § 1.181 (including Tabs A and B)
- ☒ Return Receipt Postcard

Fee calculation:

- ☒ No additional fee is required.
- ☐ Small Entity.
- ☐ An extension fee in an amount of \$_____ for a _____-month extension of time under 37 C.F.R. § 1.136(a).
- ☐ An additional filing fee has been calculated as shown below:

					Small Entity			Not a Small Entity	
	Claims Remaining After Amendment		Highest No. Previously Paid For	Present Extra	Rate	Add'l Fee	or	Rate	Add'l Fee
Total		Minus		0	x \$9=			x \$18=	
Indep.		Minus		0	x 44=			x \$88=	
First Presentation of Multiple Dep. Claim					+\$150=			+\$300=	
					Total	\$		Total	\$0

Fee payment:

- ☐ Checks in the amounts of \$_____ for the _____ fee are enclosed.
- ☐ Please charge Deposit Account No. 23-1925 in the amount of \$_____. A copy of this Transmittal is enclosed for this purpose.
- ☐ Payment by credit card in the amount of \$_____ (Form PTO-2038 is attached).
- ☒ The Director is hereby authorized to charge payment of any additional filing fees required under 37 CFR § 1.16 and any patent application processing fees under 37 CFR § 1.17 associated with this paper (including any extension fee required to ensure that this paper is timely filed), or to credit any overpayment, to Deposit Account No. 23-1925.

Respectfully submitted,

Date

12/21/06

Jason W. Schigelone (Reg. No. 56,243)

[Signature]



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12/21/06

Date of Deposit

Jason W. Schigelone, Reg. No. 56,243

Name of applicant, assignee or
Registered Representative

Signature

12/21/06
Date of Signature

Our Case No. 12730/11
Client Ref. No. PA-5327-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Thomas A. Osborne et al.

Serial No. 10/642,513

Filing Date: August 15, 2003

For Stent and Method of Forming a
Stent with Integral Barbs

Examiner: William H. Matthews

Group Art Unit No.: 3738

PETITION TO WITHDRAW FINALITY UNDER 37 C.F.R. § 1.181

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention : Fred Schmidt
Technology Center 3700 Group Director

Dear Mr. Schmidt:

Pursuant to 37 C.F.R. § 1.181, Applicants respectfully petition and request that the finality of the rejection in the present matter be withdrawn as premature.

REMARKS

On September 19, 2006, Applicants submitted a Request for Continued Examination and an Amendment which cancelled all of the then-pending claims and added new claims 45-64. (A copy of the Amendment dated September 19, 2006 is attached at Tab A.) On October 10, 2006, the Examiner mailed a first Office Action in which he finally rejected claims 45, 46, 48-50, 53, 58, and 60-62. On December 11, 2006, Applicants submitted an Amendment and Response which, *inter alia*, raised the question of prematurity of the final rejection. (A copy of the Amendment and Response dated December 11, 2006 is attached at Tab B.)

On December 18, 2006, Applicants' representative (Jason W. Schigelone, Reg. No. 56,243) had a telephone interview with the Examiner (William H. Matthews) in which the propriety of the final rejection was discussed. After reconsideration by the Examiner, no agreement was reached.

Pursuant to 37 C.F.R. §1.181, Applicants petition and submit that the final rejection is premature. Accordingly, Applicants respectfully request that the final rejection be withdrawn.

The requirements for a first Office Action Final Rejection are not met

Pursuant to MPEP 706.07(b), the Examiner may finally reject claims in a first Office Action only if "all claims of the new application (1) are drawn to the same invention claimed in the earlier application, **and** (2) would have been properly finally rejected on the grounds and art of record in the next Office Action if they had been entered in the earlier application." (emphasis added.) Because neither of these conditions is met here, the finality of the rejection is premature.

I. Claims are not drawn to the same invention claimed in the earlier application

First, the rejected claims are not "drawn to the same invention claimed in the earlier application." Prior to the first Office Action, Applicants cancelled all of the then-pending claims and submitted new claims 45-64. These new claims do not recite

features that were recited in the claims in the earlier application. For example, independent claims 45 and 58 do not recite barbs “extending in a generally transverse direction from a longitudinal axis of the stent,” nor do they recite a wire orientation step as recited in cancelled claims 21 and 31. Further, as submitted, independent claims 45 and 48 recite structural features that were not recited in the claims of the earlier application. For example, independent claims 45 and 58 as submitted require a wire that is “bent to form ... [a] bend.” Because these new claims are not “drawn to the same invention claimed in the earlier application,” they cannot be finally rejected in a first Office Action. MPEP 706.07(b).

II. Claims would not have been properly finally rejected on the grounds and art of record

The Examiner rejected claims 45, 46, 48-50, 53, 58, and 60-62 under 35 USC § 102(e) as anticipated by U.S. Patent No. 6,849,087 (“Chuter”). None of these claims, as submitted in the present application, was or would have been properly finally rejected on the grounds and art cited by the Examiner.

The rejected claims are drawn to bent wire stents having integrally formed barbs (i.e. barbs that “have not been attached to the stent wire during the manufacturing process”). See e.g., ¶ 5, Claims 45 and 58. The wire is bent to form a bend, so that the barb points in a predetermined direction. See e.g., Claims 45 and 58. In contrast, Chuter recites structures with non-integrally formed barbs (see e.g., Chuter, figure 7a; col. 8, lines 51-54 (“[h]ooks 90 may be connected to each proximal apex by welding or gluing or other suitable connecting means,”)) and structures with apices that are not bent, but instead are cut in a pattern from a cylinder (see e.g., *id.*, figure 7b; col. 8, lines 55-59).

The Examiner is mistaken in his contention that the bending limitation regards a product by process step and further that the prior art “show[s] the final structure implied by [bending],” because bending imparts “distinctive structural characteristics” that stent wires that are not “bent to form . . . [a] bend” do not possess. See MPEP 2113 (citing to *In re Garnero*, 412 F.2d 276, 279; 162 USPQ 221, 223 (CCPA, 1979), holding that 1)

the limitation “interbonded . . . by interfusion,” like the limitations “press fitted,” “etched,” and “welded,” is a structural limitation, rather than a process limitation; and 2) prior art that did not disclose an apparatus with the claimed structural characteristics did not invalidate the claims at issue).

Indeed, a stent wire that is “bent to form . . . [a] bend” has distinctive structural characteristics over stent wires that do not have such bends, for example, because bending results in plastic deformation of the wire in the bend region. Consequently, bending may induce strains in the wire that weaken or otherwise affect the mechanical and functional characteristics of the stent. *See e.g.*, ¶¶17-20 and 198-206. In contrast, the pattern of the attachment system shown in figure 7b of Chuter is cut in shape from a cylinder (Chuter, col. 8, lines 55-59) and thus does not have plastically deformed bend regions. Therefore, the apices 93, 94 of the structure shown in FIG 7b of Chuter are structurally distinct from the bends as recited in the claims submitted in the present application.

In order to anticipate under § 102, an asserted reference must teach or disclose each and every element of the claimed invention. MPEP § 2131. Because the stents recited in rejected claims 45 and 58 have structural features that are not taught or disclosed by Chuter, and because claims 46, 48-50, and 53 depend directly or indirectly from claim 45 and claims 60-62 depend directly or indirectly from claim 58, Chuter does not anticipate any of the rejected claims.

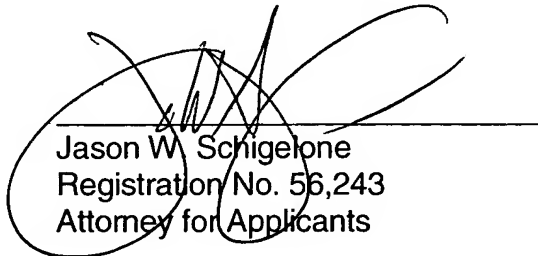
Because none of the claims as submitted in the present application was or would have been properly finally rejected on the grounds and art cited by the Examiner, the final rejection is premature. Applicants respectfully request that the finality of the rejection be withdrawn.

SUMMARY

Because the claims of the new application are not drawn to the same invention claimed in the earlier application and because the prior art of record would not have formed a proper basis for a rejection, the final rejection in the first Office Action is premature. Accordingly, Applicants respectfully petition and request that the finality of

the rejection be withdrawn and that the case be returned to the Examiner for appropriate disposition. The Director is invited to contact the undersigned attorney for the Applicants via telephone if such communication would expedite this petition.

Respectfully submitted,



Jason W. Schigelone
Registration No. 56,243
Attorney for Applicants

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Attachments: Tab A: Amendment dated September 19, 2006
Tab B: Amendment and Response dated December 11, 2006

"Express Mail" mailing label number EV 655 034 549 US

Date of Deposit: September 19, 2006



Attorney Docket No. 12730-11
Client Ref. No. PA-5327-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Thomas A. Osborne et al.

Serial No. 10/642,513

Filing Date: August 15, 2003

For Stent and Method of Forming a
Stent with Integral Barbs

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) Examiner: William H. Matthews
)
) Group Art Unit No.: 3738
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)
)
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AMENDMENT

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In reply to the Final Office Action dated May 22, 2006, please amend the above-identified application as indicated herein.

Amendments to the Claims begin on page 2.

Remarks begin on page 6.

In the Claims:

Please cancel claims 1-44 and add new claims 45-64. A complete listing of the claims appears below with proper claim identifiers.

Claims 1-44 (Cancelled)

45. (New) A barbed stent for deployment within the body of a patient, comprising:

a wire having at least one integrally formed barb configured to engage tissue adjacent the stent;

wherein the wire is bent to form at least one bend connecting to at least two struts such that the at least one barb points in a predetermined direction at an angle relative to a longitudinal axis of the stent.

46. (New) The stent of claim 45, wherein the wire is in a zigzag shape.

47. (New) The stent of claim 45, wherein the at least one barb points in a direction at an acute angle relative to the longitudinal axis of the stent.

48. (New) The stent of claim 45, wherein the at least one barb points in a direction at a generally transverse angle relative to the longitudinal axis of the stent.

49. (New) The stent of claim 45, wherein the at least one barb is positioned on the at least one bend.

50. (New) The stent of claim 45, wherein each of the at least one bend comprises at least one barb positioned thereon.

51. (New) The stent of claim 45, wherein the at least one barb is positioned on at least one of the at least two struts.

52. (New) The stent of claim 45, wherein each of the at least two struts comprises at least one barb positioned thereon.

53. (New) The stent of claim 45, wherein the stent is adjacent a proximal end of an endoluminal prosthesis.

54. (New) The stent of claim 53, wherein the at least two struts extend away from the proximal end of the endoluminal prosthesis in a proximal direction.

55. (New) The stent of claim 54, wherein the endoluminal prosthesis is adapted to be deployed at least partially within the aorta, so that the stent extends at least partially above a renal artery when the prosthesis is implanted.

56. (New) The stent of claim 53, wherein the prosthesis is a bifurcated aortic prosthesis.

57. (New) The stent of claim 45:

wherein the wire is in a zigzag shape and the at least one barb points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis of the stent, the at least one barb being positioned on one of:

a) the at least one bend; and

b) at least one of the at least two struts; and

wherein the stent is adjacent a proximal end of a bifurcated aortic endoluminal prosthesis, the at least two struts of the stent extending away from the proximal end of the endoluminal prosthesis in a proximal direction, the endoluminal prosthesis being adapted to be deployed at least partially within the aorta, so that the stent extends at least partially above a renal artery when the prosthesis is implanted.

58. (New) An endoluminal prosthesis comprising:
a substantially cannular body having proximal and distal ends; and
a stent affixed to the substantially cannular body near the proximal
end, the stent comprising a wire having at least one integrally formed barb configured to
engage tissue adjacent the stent;

wherein the wire is bent to form at least one bend connecting to at least
two struts such that the at least one barb points in a predetermined direction at an angle
relative to a longitudinal axis of the stent.

59. (New) The prosthesis of claim 58, wherein the substantially cannular body
is bifurcated.

60. (New) The prosthesis of claim 58, wherein the stent is in a zigzag shape.

61. (New) The prosthesis of claim 58, wherein the at least one barb is
positioned on one of:

- a) the at least one bend; and
- b) at least one of the at least two struts.

62. (New) The prosthesis of claim 58, wherein the at least one barb points in a
direction at one of an acute angle and a generally transverse angle relative to the
longitudinal axis of the stent.

63. (New) The prosthesis of claim 58, wherein at least a portion of the stent
extends proximally away from the proximal end of the cannular body.

64. (New) The prosthesis of claim 58:

wherein the stent is in a zigzag shape and the at least one barb points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis of the stent, the at least one barb being positioned on one of:

- a) the at least one bend; and
- b) at least one of the at least two struts; and

wherein the substantially cannular body is bifurcated and at least a portion of the stent extends proximally away from the proximal end of the cannular body.

REMARKS

Applicants respectfully request that the Examiner cancel Claims 1-40, which were previously presented and entered, without prejudice to Applicants' right to pursue these claims in a related application.

Claims 41-44 were previously presented in an Amendment dated July 24, 2006 and were not entered by the Examiner. Applicants respectfully request that the Examiner cancel Claims 41-44 without prejudice to Applicants' right to pursue these claims in a related application.

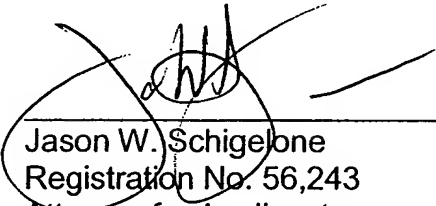
Claims 45-64 are presented by virtue of the present Amendment. No new matter has been added. Support for the newly-added claims may be found throughout the specification and in paragraphs 198-206.

New claims are drawn to various embodiments of the present invention including bent wire stents having integrally formed barbs. The stent wire is bent "such that the at least one barb points in a predetermined direction." *See, e.g.*, Claims 45 and 58. In contrast, prior art references such as Chuter (U.S. Patent No. 6,849,087) teach that the barbs can be bent to point them in their ultimate direction. Bending the barbs can induce undesirable strains in the stent; a problem that is addressed by the claimed invention. Therefore, Applicants respectfully assert that the newly presented claims are patentably distinct over the prior art.

SUMMARY

Applicants believe that the present claims are patentable and that the application is in a condition for allowance. Accordingly, Applicants respectfully request that the Examiner grant early allowance of the application. The Examiner is invited to contact the undersigned attorney for the Applicants via telephone if such communication would expedite this application.

Respectfully submitted,



Jason W. Schigelone
Registration No. 56,243
Attorney for Applicants

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December 11, 2006

Date of Deposit

Jason W. Schigelone, Reg. No. 56,243

Name of applicant, assignee or
Registered Representative

Signature

December 11, 2006

Date of Signature



Our Case No. 12730-11
Client Ref. No. PA-5327-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Thomas A. Osborne et al.

Serial No. 10/642,513

Filing Date: August 15, 2003

For Stent and Method of Forming a
Stent with Integral Barbs

Examiner: William H. Matthews

Group Art Unit No.: 3738

AMENDMENT AND RESPONSE

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In reply to the Final Office Action dated October 10, 2006, please amend the above-identified application as indicated herein.

Amendments to the Claims begin on page 2.

Remarks begin on page 6.

In the Claims:

Please amend the claims as indicated below. A complete listing of the claims appears below with proper claim identifiers.

Claims 1-44 (Cancelled)

45. (Currently amended) A barbed stent for deployment within the body of a patient, comprising:

a wire having at least one integrally formed barb configured to engage tissue adjacent the stent;

wherein the wire ~~is bent to form~~ comprises at least one bend connecting to at least two struts such that the at least one barb points in a predetermined direction at an angle relative to a longitudinal axis of the stent, wherein the at least one barb is unbent with respect to the wire and is free of weakening due to bending.

46. (Previously presented) The stent of claim 45, wherein the wire is in a zigzag shape.

47. (Withdrawn) The stent of claim 45, wherein the at least one barb points in a direction at an acute angle relative to the longitudinal axis of the stent.

48. (Previously presented) The stent of claim 45, wherein the at least one barb points in a direction at a generally transverse angle relative to the longitudinal axis of the stent.

49. (Previously presented) The stent of claim 45, wherein the at least one barb is positioned on the at least one bend.

50. (Previously presented) The stent of claim 45, wherein each of the at least one bend comprises at least one barb positioned thereon.

51. (Withdrawn) The stent of claim 45, wherein the at least one barb is positioned on at least one of the at least two struts.

52. (Withdrawn) The stent of claim 45, wherein each of the at least two struts comprises at least one barb positioned thereon.

53. (Previously presented) The stent of claim 45, wherein the stent is adjacent a proximal end of an endoluminal prosthesis.

54. (Withdrawn) The stent of claim 53, wherein the at least two struts extend away from the proximal end of the endoluminal prosthesis in a proximal direction.

55. (Withdrawn) The stent of claim 54, wherein the endoluminal prosthesis is adapted to be deployed at least partially within the aorta, so that the stent extends at least partially above a renal artery when the prosthesis is implanted.

56. (Withdrawn) The stent of claim 53, wherein the prosthesis is a bifurcated aortic prosthesis.

57. (Withdrawn) The stent of claim 45:
wherein the wire is in a zigzag shape and the at least one barb points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis of the stent, the at least one barb being positioned on one of:

- a) the at least one bend; and
- b) at least one of the at least two struts; and

wherein the stent is adjacent a proximal end of a bifurcated aortic endoluminal prosthesis, the at least two struts of the stent extending away from the proximal end of the endoluminal prosthesis in a proximal direction, the endoluminal

prosthesis being adapted to be deployed at least partially within the aorta, so that the stent extends at least partially above a renal artery when the prosthesis is implanted.

58. (Currently amended) An endoluminal prosthesis comprising:
a substantially cannular body having proximal and distal ends; and
a stent affixed to the substantially cannular body near the proximal end, the stent comprising a wire having at least one integrally formed barb configured to engage tissue adjacent the stent;
wherein the wire ~~is bent to form~~ comprises at least one bend connecting to at least two struts such that the at least one barb points in a predetermined direction at an angle relative to a longitudinal axis of the stent, wherein the at least one barb is unbent with respect to the wire and is free of weakening due to bending.

59. (Withdrawn) The prosthesis of claim 58, wherein the substantially cannular body is bifurcated.

60. (Previously presented) The prosthesis of claim 58, wherein the stent is in a zigzag shape.

61. (Previously presented) The prosthesis of claim 58, wherein the at least one barb is positioned on one of:

- a) the at least one bend; and
- b) at least one of the at least two struts.

62. (Previously presented) The prosthesis of claim 58, wherein the at least one barb points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis of the stent.

63. (Withdrawn) The prosthesis of claim 58, wherein at least a portion of the stent extends proximally away from the proximal end of the cannular body.

64. (Withdrawn) The prosthesis of claim 58:

wherein the stent is in a zigzag shape and the at least one barb points in a direction at one of an acute angle and a generally transverse angle relative to the longitudinal axis of the stent, the at least one barb being positioned on one of:

- a) the at least one bend; and
- b) at least one of the at least two struts; and

wherein the substantially cannular body is bifurcated and at least a portion of the stent extends proximally away from the proximal end of the cannular body.

REMARKS

Election/Restriction:

Applicants acknowledge the Examiner's entry of the restriction requirement.

Finality of the Rejection:

Applicants note the Examiner's entry of a final rejection on the first Office Action. Applicants submit that this final rejection is premature. MPEP 706.07(c).

Pursuant to MPEP 706.07(b), the Examiner may finally reject claims in a first Office Action only if "all claims of the new application (1) are drawn to the same invention claimed in the earlier application, and (2) would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application." (emphasis added). Because neither of these conditions is met here, the finality of the rejection is premature.

First, the rejected claims are not "drawn to the same invention claimed in the earlier application." Prior to the first Office Action, Applicants cancelled all of the then-pending claims and submitted new claims 45-64. These new claims do not recite features that were recited in the claims in the earlier application. For example, independent claims 45 and 58 do not recite barbs "extending in a generally transverse direction from a longitudinal axis of the stent," nor do they recite a wire orientation step. See *e.g.*, cancelled claims 21 and 31. Further, as submitted, independent claims 45 and 48 recite structural features that were not recited in the claims of the earlier application. For example, independent claims 45 and 58 as submitted require a wire that is "bent to form ... [a] bend." Because these new claims are not "drawn to the same invention claimed in the earlier application," they cannot be finally rejected in a first Office Action. MPEP 706.07(b).

Second, none of claims 45-64, as submitted in the present application, was or would have been properly finally rejected on the grounds and art cited by the Examiner.

For example, as explained below in greater detail, the cited art does not disclose a stent having all of the recited structural features, including a wire stent having an integrally formed barb, and that is bent to form a bend, so that the barb points in a predetermined direction. In contrast, the cited art recites structures with non-integrally formed barbs and/or structures with unbent apices. A wire that is bent to form a bend has plastically deformed bend regions, unlike structures with unbent apices. Bending may induce strains in the wire that weaken or otherwise affect the characteristics of the stent. Consequently, a wire that is bent to form a bend has distinctive structural characteristics over stent wires that do not have such bends.

Applicants filed a Request for Continued Examination, paid the required fee, and submitted new claims that are distinguishable over the art of record. Accordingly, the finality of the rejection is premature. Applicants respectfully request that the Examiner withdraw the finality of the rejection.

In the Claims:

Claims 45, 46, 48-50, 53, 58, and 60-62 are currently pending in this application. Applicants have amended Claims 45 and 58 to more particularly emphasize the novelty of the claimed invention. No new matter has been added by virtue of these amendments. Support for the amendments may be found throughout the specification, and especially in paragraphs 198-206.

Independent claims 45 and 58 are drawn to stents made from wire and having integrally formed barbs. As mentioned in the background section of the present application, one of the issues in the prior art is that, in use, the barbs on a wire stent can separate from the wire due to internal body forces acting on the stent, such as cyclical loading caused by cardiovascular pulsatile forces. Such forces can cause mechanical fatigue and failure at the barb-stent junction. See e.g., ¶¶17-20.

Wire stents with non-integral barbs may be prone to fracture, detachment, and the like, because the junction between the wire and the barb acts as a stress concentrator and because the chemically and/or mechanically-modified junction has a tendency to corrode when subjected to a saline, oxygen-rich physiological environment.

See e.g., ¶¶18-19. Similarly, wire stents with barbs that are oriented by bending or plastically deforming the barb may also be susceptible to mechanical fatigue and failure because bending the barb can induce undesirable strains in the stent that weaken the barb-stent junction. See e.g., ¶¶17-20 and 198-206.

The presently claimed invention addresses these problems by providing a wire stent with an integral barb that points in a predetermined direction. In contrast with the prior art, where such a barb is pointed by bending or plastically deforming the barb with respect to the wire, here, the at least one barb is unbent, and is free of weakening due to bending. See e.g., Claims 45 and 58.

Such a stent is structurally distinct over prior art wire stents. First, the barb and the wire are integral and “have not been attached to the stent wire during the manufacturing process.” See e.g., ¶ 5. Consequently, stents as claimed may be less prone to corrosion and fracture, and will be better able to accommodate and distribute bending and shear stresses via the barb. See e.g., ¶19. Second, the barb is unbent and is not plastically deformed, or weakened, like prior art barbs. Consequently, the barb-stent junction may be stronger, and such stents may be less prone to barb separation due to mechanical fatigue.

The prior art of record does not disclose a stent as recited in each of the claims of the present application. Accordingly, Applicants assert that these claims are allowable and respectfully request notice to this effect.

Claim Rejections under 35 USC § 102(e)

The Examiner rejected claims 45, 46, 48-50, 53, 58, and 60-62 under 35 USC § 102(e) as anticipated by U.S. Patent No. 6,849,087 (“Chuter”).

Chuter does not teach or disclose a stent with all of the structural features recited in the rejected claims. In particular, the rejected claims are drawn to a wire stent having an integrally formed barb, where the wire is bent to form a bend, so that the barb points in a predetermined direction. In contrast, Chuter recites structures with non-integrally formed barbs (see e.g., Chuter, figure 7a; col. 8, lines 51-54 (“[h]ooks 90 may be connected to each proximal apex by welding or gluing or other suitable connecting

means,")) and structures with apices that are not bent, but instead are cut in a pattern from a cylinder (see e.g., *id.*, figure 7b; col. 8, lines 55-59).

The Examiner is mistaken in his contention that the bending limitation regards a product by process step and further that the prior art "show[s] the final structure implied by [bending]," because bending imparts "distinctive structural characteristics" that stent wires that are not "bent to form . . . [a] bend" do not possess. See MPEP 2113 (citing to *In re Garnero*, 412 F.2d 276, 279; 162 USPQ 221, 223 (CCPA, 1979), holding that 1) the limitation "interbonded . . . by interfusion," like the limitations "press fitted," "etched," and "welded," is a structural limitation, rather than a process limitation; and 2) prior art that did not disclose an apparatus with the claimed structural characteristics did not invalidate the claims at issue).

Indeed, a stent wire that is "bent to form . . . [a] bend" has distinctive structural characteristics over stent wires that do not have such bends, for example, because bending results in plastic deformation of the wire in the bend region. Consequently, bending may induce strains in the wire that weaken or otherwise affect the mechanical and functional characteristics of the stent. See e.g., ¶¶ 17-20 and 198-206. In contrast, the pattern of the attachment system shown in figure 7b of Chuter is cut in shape from a cylinder (Chuter, col. 8, lines 55-59) and thus does not have plastically deformed bend regions. Therefore, the apices 93, 94 of the structure shown in FIG 7b of Chuter are structurally distinct from the bends as recited in the claims submitted in the present application.

In order to anticipate under § 102, an asserted reference must teach or disclose each and every element of the claimed invention. MPEP § 2131. Because the stents recited in rejected claims 45 and 58 have structural features that are not taught or disclosed by Chuter, and because claims 46, 48-50, and 53 depend directly or indirectly from claim 45 and claims 60-62 depend directly or indirectly from claim 58, Chuter does not anticipate any of the rejected claims. Consequently, none of the claims as submitted in the present application was, or would have been properly finally rejected on the grounds and art cited by the Examiner and so the finality of the rejection is

premature. Applicants respectfully request that the Examiner withdraw the final rejection.

Independent claims 45 and 58 have been amended to further emphasize the novelty of the claims over the prior art. Claims 45 and 58 as amended require, *inter alia*, a wire stent with at least one integral barb where the barb "points in a predetermined direction . . . [and] is unbent with respect to the wire." (Emphasis added). Such wire stents have barbs that are "free of weakening due to bending," in contrast with prior art stents that include bent barbs.

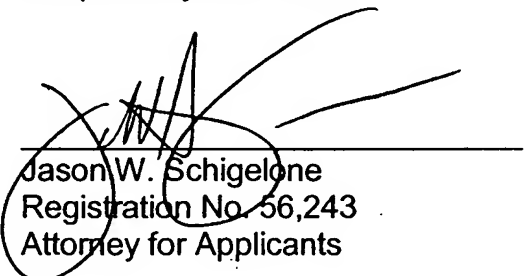
Chuter clearly contemplates attachment systems with non-integrally formed barbs and barbs that are bent. See e.g. Chuter, figures 7a-7b; col. 8, lines 51-54; col. 8, lines 64-65 ("[h]ooks 96 may be added, either by shaping them from the continuous cylinder, or by welding or gluing them on." (emphasis added)). Such attachment systems are structurally and functionally different than the claimed stents where the barbs are integral with the wire and are unbent. Bending the barb with respect to the wire causes plastic deformation that may induce undesirable strains in, and weaken the stent. See e.g., ¶¶ 17-20 and 198-206. Consequently, stents as presently claimed are an improvement over the stents recited in Chuter.

Chuter fails to teach or disclose each and every structural limitation of independent claims 45 and 58 and therefore does not anticipate the claimed invention. Claims 46, 48-50, and 53 depend directly or indirectly from claim 45 and claims 60-62 depend directly or indirectly from claim 58. Accordingly, Chuter does not anticipate any of these claims. Applicants respectfully request that the rejection of Claims 45, 46, 48-50, 53, 58, and 60-62 be withdrawn and that the claims be allowed to pass to issuance. Early notification to such effect is earnestly solicited.

SUMMARY

Because the prior art of record does not and would not have formed a proper basis for rejection, the final rejection in the first Office Action is premature. Applicants believe that the claims in the present application are patentable and that the application is in a condition for allowance. Applicants respectfully request that the finality of the Office Action be withdrawn and that the Examiner grant allowance of the application. The Examiner is invited to contact the undersigned attorney for the Applicants via telephone if such communication would expedite this application.

Respectfully submitted,



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